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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,026

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Hideaki Yamaoka

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04/28/2008

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EXAMINER

MEAH, MOHAMMAD Y

ART UNIT

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1652

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,026	Applicant(s) YAMAOKA ET AL.	
	Examiner MD. YOUNUS MEAH	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/31/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-9,11-14 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-9,11-14 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 6-9, 11-14 and 24 were examined in the previous action. Claims 1, 6-9, 11-14 and 24 are pending.

Claim Rejections

CLAIM Rejection - 35 U.S.C 103a

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claims 1, 6-9, 11-14 and 24 under 35 U.S.C. 103(b) by Shimomura et al (Anal biochem 1986 vol 153, pp 126-131) in view of Sode et al. (WO 02/36779, English translation in US 20-04/0023330) remain as discussed below:

Claims 1, 6-9, 11-14 and 24 are directed to the purification of *Burkholderia* GDH protein comprising α , β , γ subunits using liquid chromatography comprising ion exchange (resin comprising quaternary ammonium group) and using eluent containing cholate.

Shimomura et al teaches the purification of Cytochrome bc (a protein having electron transfer and GDH unit) protein using liquid chromatography comprising phenyl-sepharose and ion exchange (DEAE; diethylaminoethyl) sepharose column, wherein eluent is applied at constant gradient containing 0.25% cholate.

Sode teaches GDH protein from microorganism *Burkholderia Cepacia* comprising α , β , γ subunit and teaches expression of said protein in *E. coli* and also teaches the purification of said GDH protein by column and ion-exchange chromatography using DEAE-Toyopearl column using a buffer at pH 8.0. However Sode et al. does not teach the elution of said columns with a hydroxyl cholate gradient. Advantageous use of cholate as an eluent in hydrophobic-interaction liquid chromatography to purify Cy GDH proteins is well documented (Shimomura et al (Anal biochem 1986 vol 153, pp 126-131). As such it would have been obvious to one of ordinary skill in the art to obtain GDH protein comprising α , β , γ subunit from microorganism *Burkholderia Cepacia* or said GDH produced by transformant such as *E. coli* taught by Sode and use the method of purification using liquid chromatography comprising phenyl-sepharose and ion exchange (DEAE (diethyl amino ethyl ion exchange) sepharose column, wherein eluent is applied at constant gradient containing 0.25% cholate as taught by Shimomura et al.

Applicants' argument that Sode did not use ion exchange chromatography is not found to be true. On the contrary as described by Sode (see Purification of enzyme section paragraph 173-175)

“ The dialyzed enzyme was applied to a DEAE-5PW column (8.0 mm ID .times.7.5 cm, Tosoh Corporation, Tokyo, Japan). This column was equilibrated beforehand with 10 mM potassium phosphate buffer (pH 6.0) containing 0.2% Triton X-100. The proteins were eluted with a linear gradient of 0 to 100 mM NaCl in 10 mM potassium phosphate buffer (pH 8.0). The flow rate was 1 ml/min. Fractions exhibiting the GDH activity were eluted at a NaCl concentration of about 20 mM. The fractions having the GDH activity

were collected and desalted overnight with 10 mM potassium phosphate buffer (pH 8.0) containing 0.2% Triton X-100 to obtain the purified enzyme”

The DEAE-5PW column contain ion exchange resin comprising quaternary amino group (DEAE: Diethylaminoethyl; at ~ pH 6 becomes quaternary amino group)

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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